REMARKS

In the Claims:

Claims 22-26 are currently pending.

Claim Rejections:

35 U.S.C. § 101

Applicants respectfully traverse the present rejections and request continued examination in light of the newly submitted evidence and arguments.

Claims 22-26 stand rejected under 35 U.S.C. § 101 for alleged lack of utility. Although the Office action acknowledges that the MLR assay is useful for screening compounds that play a role in immune response, Page 3 of the Office action mailed 9-19-07, the Office action rejects Applicants' reliance on the MLR assay in this case because allegedly "[t]he ability of the claimed protein to stimulate or inhibit lymphocyte proliferation in the MLR assay does not provide support for what specific conditions or for which specific diseases the claimed invention would predictably function for a therapeutic suppression of the immune system." Page 4 of the Office action mailed 12-31-07.

Applicants respectfully disagree. In the declaration of Sherman Fong, Ph.D., submitted with the Amendment and Request for Reconsideration mailed August 3, 2005, Dr. Fong attests that it is "his considered scientific opinion that a PRO polypeptide shown to inhibit T-cell proliferation in the MLR assay where the activity is observed as 80% or less of the control, one of skill in the art would expect to find a practical utility when an inhibition of the immune response is desired such as in autoimmune diseases." According to the Manual of Patent Examining Procedure (the "MPEP"), Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided that shows that one of ordinary skill in the art would have a legitimate basis to doubt the credibility of such a statement.

Applicants respectfully draw the Examiner's attention to the Utility Examination Guidelines, Part IIB, 66 Fed. Reg. 1098 (2001), which state, "Office personnel must accept an opinion from a qualified expert that is based upon relevant facts whose accuracy is not being questioned; it is improper to disregard the opinion solely because of a disagreement over the significance or meaning of the facts offered." Thus, barring evidence to the contrary regarding the above statement in the Fong Declaration, this rejection is improper under both the case law and the Utility guidelines.

Additionally, the Office action alleges that the present application provides "insufficient data . . . to conclude anything regarding the ability of an antibody that binds to the polypeptide PRO361 of the invention to be used in a substantial way to therapeutically inhibit an immune response, and much more experimentation would be required to use the invention in this manner." Page 5 of the Office action mailed 12-31-07.

Applicants respectfully disagree. In light of the substantial evidence previously submitted by Applicants, and in light of Applicants' assertion of utility in the specification based on test results of the MLR assay, no explicit data of the results of PRO361 in the MLR assay are required to demonstrate an adequate utility. However, while Applicants respectfully disagree with this ground of rejection, Applicants herein submit a declaration of the inventors more fully explaining the MLR assay as utilized in connection with the present invention. In addition, Exhibit A of the attached declaration provides additional data demonstrating that PRO361 significantly inhibits lymphocyte proliferation in the MLR assay. Specifically, at a 1.5 nM concentration, PRO361 exhibited mean inhibition values of 63.2 and 77.3. At a 15 nM concentration, PRO361 exhibited mean inhibition values of 64.7 and 99.4. Every value shows a decrease relative to control, which demonstrates inhibition.

Indeed, three of the four values are below the preferred 80% value, which clearly demonstrates that it is more likely than not that PRO361 may be used as Applicants assert. For example, in the related field of pharmaceutical arts, practical utility may be shown by adequate evidence of any pharmacological activity. Test results ***need not absolutely prove that the compound is pharmacologically active*** to prove practical utility. Rather, all that is required is that the tests be reasonably indicative of the desired

pharmacological response. In other words, there must be a sufficient correlation between the tests and an asserted pharmacological activity so as to convince those skilled in the art, to a ***reasonable*** probability, that the novel compound will exhibit the asserted pharmacological behavior. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 39 USPQ2d 1895 (Fed. Cir. 1996). The present specification provides sufficient information for one of ordinary skill in the art to conclude that the MLR assay results are reasonably indicative of the asserted utility, particularly when coupled with the data submitted with the attached declaration.

Additionally, Applicants continue to rely on (1) withdrawal of the utility rejection in ***two*** related cases, U.S. Patent Application Nos. 09/944,929 and 10/677,471, which claim PRO361 nucleic and amino acid sequences, and (2) on issuance of ***two*** U.S patents, Nos. 7,220,835 and 7,282,570, which are assigned to Genentech, and which share specifications similar to the specification at issue and contain claims that rely on an assertion of utility based on results obtained in the MLR assay. The Office action rejects this evidence, however, "because each application is examined on its own merit and support therein." Page 5 of the Office action mailed December 31, 2007. Applicants respectfully disagree that this evidence is unpersuasive. According to the Court of Customs and Patent Appeals, **"similar claims allowed by the Patent Office tribunals furnish evidence of what features those tribunals regard as patentable**." *In re Schecter and LaForge,* 205 F.2d 185, 98 USPQ 144, 150 (CCPA 1953). Thus, withdrawal of the rejection under 35 U.S.C. § 101 in two related applications, and issuance of two similar patents that rely on substantially identical assertions of utility, provides persuasive evidence that the present claims are supported by an adequate utility. In fact, U.S. Patent No. 7,282,570, in which assignee of the present application, Genentech, Inc. asserted utility based on results in the MLR assay, issued with antibody claims identical to the claims at issue here but for the fact that the antibody of U.S. Patent No. 7,282,570 binds a protein different than PRO361. This provides even further persuasive evidence that the PTO views Applicants' asserted utility for the claimed invention as sufficient to satisfy the requirements of 35 USC § 101.

Indeed, as noted, the PTO cautions that rejections for lack of utility are rarely sustained by federal courts. MPEP § 2107.02 III B, citing *In re Gazave,* 379 F.2d 973 (CCPA

1967) (emphasis in original). A utility rejection is not proper unless the PTO establishes that it has reason to doubt the objective truth of the statements contained in the written description. The PTO may establish a reason to doubt an inventor's asserted utility when:

(1) the written description suggests an inherently unbelievable undertaking; or

(2) the written description suggests a utility that involves implausible scientific principles.

In re Cortright, 165 F.3d 1353, 49 USPQ2d 1464 (Fed. Cir. 1999). The evidence discussed above clearly demonstrates that the present specification does not assert any inherently unbelievable undertaking nor does it suggest a utility that involves implausible scientific principles.

In the present case there is no evidence that the asserted utility of PRO361, based on its activity in the MLR assay, would be considered 'false' by a person of ordinary skill in the art. Rather, as stated above, the Office has recognized that the MLR assay is art-recognized and accepted for identifying molecules that suppress an immune response. Further, in addition to explaining how to conduct the MLR assay, Example 34 of the present specification, through reference to the *Current Protocols in Immunology,* also explains how to calculate the results obtained from the MLR assay. One of ordinary skill in the art could easily carry out the MLR assay as described in the specification and *Current Protocols,* and calculate the results as taught by the specification and *Current Protocols.* Applicants have provided sufficient detail in the specification, about the MLR assay, how the assay is performed, what controls are used and how they are used, and how the data is calculated. Moreover, at page 141 of the specification, Applicants assert that PRO361 exhibited a significant inhibitory effect in the MLR assay. That assertion is based upon the fact that PRO361 "tested positive" in the MLR assay. According to the specification the standard for identifying immunosuppressive molecules using the MLR assay is as follows: "[a]ny decreases below control is considered to be a positive result for an inhibitory compound, with decreases of less than or equal to 80% being preferred. However, any value less than control indicates an inhibitory effect for the test protein." This standard is art recognized. For example,

the Declaration of Sherman Fong, Ph.D., previously submitted by Applicants with the Amendment and Response mailed September 2, 2005, provides evidence that one of at least ordinary skill in the art accepts this standard. Indeed, Dr. Fong is identified as an inventor on both U.S. Patent Nos. 7,220,835 and 7,282,570. Each of these patent documents set forth the *same* standard for assessing immunosuppressive ability of a test protein as is set forth in the present application. *See* US Patent No. 7,220,835, col. 383, ll 18-22 and US Patent No. 7,282,570, Example 9. *See also* US Patent No. 5,958,403 at col. 6, ll 16-19.

Furthermore, Applicants have provided herein explicit data of the results of PRO361 in the MLR assay, which clearly demonstrates inhibition of T-lymphocyte proliferation in the MLR assay by PRO361. Thus, based on this substantial evidence it is at least **reasonably** probable that PRO361 has utility as asserted by Applicants based on the immunosuppressant characteristics pr PRO361.

Moreover, while Applicants have provided the Fong Declaration, which clearly states that one of at least ordinary skill in the art does not find the asserted utility to violate or contravene any established scientific principles, and have cited several patents, including US Patent Nos. 7,220,385 and 7,282,570, as evidence that Applicants' asserted utility is art-recognized and accepted, the Office has not provided any evidence showing that the asserted utility would be considered "false" by a person of skill in the art. Thus, Applicants have provided sufficient proof of utility for claims 22-26 and respectfully request that this ground of rejection be withdrawn.

Rejection under 35 U.S.C. § 112, first paragraph:
Enablement

Claims 22-26 also stand rejected under 35 U.S.C. § 112, first paragraph because allegedly one of ordinary skill in the art would not know how to make and use the claimed invention because allegedly the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Applicants respectfully disagree. As discussed above, the claimed antibody has the specific, substantial, and credible utility of binding a polypeptide that inhibits the

proliferation of stimulated T-lymphocytes as demonstrated in the MLR assay experiment discussed in Example 34 at page 141 of the application. Applicants respectfully request the Examiner reconsider and withdraw the rejection of the claims under 35 U.S.C. § 112 ¶1 for alleged inadequate disclosure on how to use the claimed invention.

CONCLUSION

Applicants believe this Request for Continued Examination fully responds to the Office action mailed December 31, 2007. Applicants respectfully request the Examiner grant allowance of pending claims 22-26. The Examiner is invited to contact the undersigned attorney for the Applicant via telephone if such communication would expedite allowance of this application.

Respectfully submitted,

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